

REMARKS

I.      *Status Summary*

Claims 1-11 are pending in the present application and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 1-5, 9 and 10 have previously been withdrawn. Claims 6-8 and 11 presently stand rejected.

The claim for foreign priority is objected to upon the contention that a certified English translation of the foreign application has not been filed.

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Goueli et al. (1997, *Promega Notes Magazine* 63:7-9; hereinafter "Goueli et al.").

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Finnie et al. (1995, *Proc. Natl. Acad. Sci.* 92:320-324; hereinafter "Finnie et al.").

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Loong et al. (2004, *Oncogene* 23:5562-5566; hereinafter "Loong et al.").

Claims 6-8 and 11 have been rejected under 35 U.S.C. 103(a) upon the contention that the claims are unpatentable over Goueli et al. in view of Finnie et al., and in further view of Moll et al. (1999, *Oncogene* 18:3114-2126; hereinafter "Moll et al.").

Claims 6-8 and 11 have been rejected under 35 U.S.C. 103(a) upon the contention that the claims are unpatentable over Loong et al. in view of Moll et al.

Claim 6 has been canceled without prejudice. The dependency of claim 8 has been amended. No new matter has been added.

New claims 12-17 have been added. Support for new claims 12-17 can be found throughout the specification as originally filed and particularly at page 1, lines 13-17; page 12, lines 11-15; and page 19, lines 7-10. No new matter has been added.

Reconsideration of the application as amended and based on the remarks set forth below is respectfully requested.

II. Response to the Objection to the Foreign Priority Claim

The claim for foreign priority is objected to upon the contention that a certified English translation of the foreign application (PCT/JP2003/007079) has not been filed.

Applicants submit herewith a certified English translation of PCT Patent Application PCT/JP2003/007079 from which the subject patent application claims priority under 35 U.S.C. § 119(a)-(d). Accordingly, applicants respectfully submit that instant application should be afforded the priority date of June 4, 2003.

III. Response to the Rejection of Claims 6 and 11 Under 35 U.S.C. § 102(b) over Goueli et al.

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Goueli et al. The Patent Office contends that Goueli et al. teaches each and every element of the claims. In particular, the Patent Office contends that Goueli et al. teaches a method of quantitating DNA-dependent PK activity from HeLa cells. Further, the Patent Office contends that HeLa cells are cervical cells which are derived from the uterus.

The positions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claim 6 has been canceled herein, thereby mooting this rejection as it pertains to this claim.

Applicants note that it is well settled that for a cited reference to qualify as prior art under 35 U.S.C. § 102, each element of the claimed subject matter must be disclosed within the reference. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." Hybritec, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Thus,

applicants respectfully submit that for the cited reference to be an anticipation reference under 35 U.S.C. §102, the reference must disclose each and every element of the claimed subject matter.

Applicants respectfully submit that claim 11 recites, *inter alia*, measuring DNA-dependent PK and determining susceptibility of the test subject to cancer. Goueli et al. does not teach or suggest determining susceptibility of a test subject to cancer. Moreover, Goueli et al. appears to make no mention of cancer in any context. Applicants respectfully submit that simply measuring DNA-dependent PK is not tantamount to determining susceptibility of a test subject to cancer. Accordingly, applicants respectfully submit that Goueli et al. does not disclose each and every element of the claimed subject matter and therefore does not support a rejection under 35 U.S.C. §102.

Therefore, applicants respectfully submit that the claim 11 is believed to be novel over Goueli et al. Thus, applicants respectfully request that the rejection of claim 11 under 35 U.S.C. § 102(b) be withdrawn, and request that claim 11 be allowed at this time.

IV. Response to the Rejection of Claims 6 and 11 Under 35 U.S.C. § 102(b) over Finnie et al.

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Finnie et al. The Patent Office contends that Finnie et al. teaches each and every element of the claims. In particular, the Patent Office contends that Finnie et al. teaches a method of measuring DNA-dependent PK in mammalian cell extracts from HeLa cells and human 1BR cells.

The positions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claim 6 has been canceled herein, thereby mooting this rejection as it pertains to this claim.

Applicants respectfully submit that claim 11 recites, *inter alia*, measuring DNA-dependent PK and determining susceptibility of the test subject to cancer. Finnie et al. does not teach or suggest determining susceptibility of a test subject to cancer. Finnie et al. makes no mention of cancer or cancer screening. Applicants respectfully submit that disclosing a method of measuring DNA-dependent PK is not tantamount to determining susceptibility of a test subject to cancer. Accordingly, applicants respectfully submit that Finnie et al. does not disclose each and every element of the claimed subject matter and therefore does not support a rejection under 35 U.S.C. §102.

Therefore, applicants respectfully submit that the claim 11 is believed to be novel over Finnie et al. Thus, applicants respectfully request that the rejection of claim 11 under 35 U.S.C. § 102(b) be withdrawn, and request that claim 11 be allowed at this time.

V. Response to the Rejection of Claims 6 and 11 Under 35 U.S.C. § 102(b)  
over Loong et al.

Claims 6 and 11 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Loong et al. The Patent Office contends that Loong et al. teaches each and every element of the claims. In particular, the Patent Office contends that Loong et al. teaches a method of detecting DNA-dependent PK activity in cells derived from a patient with breast cancer (LB0003), cells derived from a patient with cervix carcinoma (LB0004) and control cell lines.

The positions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claim 6 has been canceled herein, thereby mooted this rejection as it pertains to this claim.

Loong et al. was published on June 7, 2004. The priority date of the instant patent application is June 4, 2003. In view of the enclosed certified copy of the priority document, the instant application should be afforded the June 4, 2003 priority

date. Accordingly, Loong et al. is not believed to constitute prior art under 35 U.S.C. § 102, thereby obviating the instant rejection over Loong et al. Thus, applicants respectfully request that the rejection of claim 11 under 35 U.S.C. § 102(b) be withdrawn, and request that claim 11 be allowed at this time.

VI. Response to the Rejection of Claims 6-8 and 11 Under 35 U.S.C. § 103(a)  
over Goueli et al., Finnie et al. and Moll et al.

Claims 6-8 and 11 have been rejected under 35 U.S.C. 103(a) upon the contention that the claims are unpatentable over Goueli et al. in view of Finnie et al., and in further view of Moll et al. The Patent Office contends that Goueli et al. teaches each and every element of the claims except that Goueli et al. does not teach the disclosed method wherein the DNA-dependent protein kinase activity in cells derived for the test subject is compared to the kinase activity in cells from a healthy subject and the cells are lymphoid cells. However, the Patent Office contends that Finnie et al. compensates for this deficiency by teaching a method of measuring DNA-dependent PK in mammalian cell extracts from HeLa cells and human 1BR cells from healthy subjects. Additionally, the Patent Office alleges that Moll et al. describes DNA-dependent PK expression in normal human lymphoid tissues. Accordingly, the Patent Office contends that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assay lymphoid cells, as well as compare DNA-dependent PK activity in these cells and cells from healthy subjects to establish cancer susceptibility and treatment in regard to DNA-dependent PK. Further, according to the Patent Office one of ordinary skill in the art would have been motivated to assay all of these types of cells because the secondary references show results from several studies suggesting DNA-dependent PK is a critical factor in a variety of cellular functions including cell growth, development and cell death.

The positions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claim 6 has been canceled herein, thereby mooting this rejection as it pertains to this claim.

Applicants respectfully submit that claims 7 and 11 recite, *inter alia*, measuring DNA-dependent PK and determining whether the test subject has an increased likelihood of developing cancer (claim 7) or determining susceptibility of the test subject to cancer (claim 11). Neither Goueli et al. nor Finnie et al. teach or suggest determining whether the test subject has an increased likelihood of developing cancer or determining susceptibility of a test subject to cancer. Neither Goueli et al. nor Finnie et al. mention cancer in any context. Applicants respectfully submit that simply measuring DNA-dependent PK is not tantamount to determining susceptibility of a test subject to cancer. Accordingly, applicants respectfully submit that both Goueli et al. and Finnie et al. suffer from significant weakness in teaching the claimed subject matter.

Moll et al. does not compensate for the deficiencies in either Goueli et al. or Finnie et al. Moll et al. does not teach or suggest measuring DNA-dependent protein kinase activity and correlating it with cancer susceptibility. Thus, Moll et al. does not compensate for the deficiencies of Goueli et al. and Finnie et al. Therefore, none of Goueli et al., Finnie et al. nor Moll et al., alone or in combination, teach or suggest each and every element of claims 7 and 11.

Further, applicants respectfully submit that one of ordinary skill in the art would not be motivated to combine the references as proposed by the Patent Office to arrive at the presently claimed subject matter. In particular, the proposed combination of references provides no motivation for measuring DNA-dependent PK to determine a subject's susceptibility of cancer. The Patent Office, at page 6, bridging page 7, of the Official Action, contends that one of ordinary skill in the art would have been motivated to assay all of these types of cells because protein kinases are a critical factor in a variety of cellular functions including cell growth, development, and cell death. However, even assuming *arguendo* that one of ordinary skill in the art would be motivated to assay a variety of cells for DNA-

dependent PK, this provides no motivation for measuring DNA-dependent PK to determine cancer susceptibility as presently claimed. Given that Goueli et al. and Finnie et al. fail to even mention cancer, it is unclear how the proposed combination of references would provide such motivation absent impermissible hindsight reconstruction.

Also, applicants respectfully submit that one of ordinary skill in the art would have no reasonable expectation of success in combining the cited references to arrive at the claimed subject matter. Given the lack of disclosure pertaining to cancer, cancer susceptibility, or the relationship between DNA-dependent PK and cancer susceptibility in the cited references, one of ordinary skill in the art would have little expectation of success in developing a method of assessing a subject's susceptibility to cancer based solely upon the disclosures of these references.

Taken together, applicants respectfully submit that the Patent Office has failed to present a *prima facie* case of obviousness over the proposed combination of Goueli et al., Finnie et al. and Moll et al. It is respectfully submitted that one of ordinary skill in the art would not have considered the presently disclosed and claimed subject matter obvious over the cited references at the time of filing.

Accordingly, applicants respectfully submit that the claims 7 and 11 are believed to be patentable over Goueli et al., Finnie et al. and Moll et al. Further, as claim 8 depends from claim 7, it too is believed to be patentable over the cited references. Thus, applicants respectfully request that the rejection of claims 7, 8 and 11 under 35 U.S.C. § 103(a) over Goueli et al., Finnie et al. and Moll et al. be withdrawn, and request that claims 7, 8 and 11 be allowed at this time.

VII. Response to the Rejection of Claims 6-8 and 11 Under 35 U.S.C. § 103(a)  
over Loong et al. and Moll et al.

Claims 6-8 and 11 have been rejected under 35 U.S.C. 103(a) upon the contention that the claims are unpatentable over Loong et al. in view of Moll et al. The Patent Office contends that it would have been obvious to one of ordinary skill in the art to combine Loong et al. and Moll et al. to arrive at the claimed subject matter.

The positions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

Initially, applicants respectfully submit that claim 6 has been canceled herein, thereby mooting this rejection as it pertains to this claim.

Further, applicants respectfully refer to the discussion hereinabove regarding Loong et al. as applied under 35 U.S.C. § 102(b). Since Loong et al. does not constitute prior art is cannot be relied upon to support a rejection under 35 U.S.C. § 103(a). Thus, applicants respectfully request that the rejection of claims 7, 8 and 11 under 35 U.S.C. § 103(a) over Loong et al. and Moll et al. be withdrawn, and request that claims 7, 8 and 11 be allowed at this time.

NEW CLAIMS

New claims 12-17 have been added. Support for new claims 12-17 can be found throughout the specification as originally filed and particularly at page 1, lines 13-17; page 12, lines 11-15; and page 19, lines 7-10. No new matter has been added.

New claims 12-17 depend from claims 7 and 11. As such, applicants respectfully submit that claims 12-17 are believed to be patentable over the cited art for at least the reasons set forth hereinabove with respect to claims 7 and 11. Accordingly, applicants respectfully request a Notice of Allowance for new claims 12-17.



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CONCLUSION

In light of and upon entry of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Office has had an opportunity to review the above Remarks, the Patent Office is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

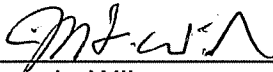
The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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